

NIOSH HAZARD REVIEW

Health Effects of Occupational Exposure to Respirable Crystalline Silica

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
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Foreword

Silicosis is the disease most associated with crystalline silica exposure; it is incurable but preventable. This debilitating and often fatal lung disease persists worldwide despite long-standing knowledge of its cause and methods for controlling it.

This Hazard Review, *Health Effects of Occupational Exposure to Respirable Crystalline Silica*, describes published studies and literature on the health effects of occupational exposure to respirable crystalline silica among workers in the United States and many other countries. The review indicates a significant risk of chronic silicosis for workers exposed to respirable crystalline silica over a working lifetime at the current Occupational Safety and Health Administration (OSHA) permissible exposure limit (PEL), the Mine Safety and Health Administration (MSHA) PEL, or the National Institute for Occupational Safety and Health (NIOSH) recommended exposure limit (REL). In addition to the risk of silicosis, epidemiologic studies indicate that workers exposed to respirable crystalline silica have an increased risk of developing lung cancer, pulmonary tuberculosis, and airways diseases. The latest scientific information also indicates possible associations of occupational exposure to silica dust with various other adverse health effects.

Until improved sampling and analytical methods are developed for respirable crystalline silica, NIOSH will continue to recommend an exposure limit of 0.05 mg/m³ as a time-weighted average (TWA) for up to a 10-hr workday during a 40-hr workweek. NIOSH also recommends substituting less hazardous materials for crystalline silica when feasible, using appropriate respiratory protection when source controls cannot keep exposures below the REL, and making medical examinations available to exposed workers.



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Abstract

Occupational exposures to respirable crystalline silica are associated with the development of silicosis, lung cancer, pulmonary tuberculosis, and airways diseases. These exposures may also be related to the development of autoimmune disorders, chronic renal disease, and other adverse health effects. Recent epidemiologic studies demonstrate that workers have a significant risk of developing chronic silicosis when they are exposed to respirable crystalline silica over a working lifetime at the current Occupational Safety and Health Administration (OSHA) permissible exposure limit (PEL), the Mine Safety and Health Administration (MSHA) PEL, or the National Institute for Occupational Safety and Health (NIOSH) recommended exposure limit (REL).

This NIOSH Hazard Review (1) examines the health risks and diseases associated with occupational exposures to respirable crystalline silica, (2) discusses important findings of recent epidemiologic studies, (3) provides the reader with sources of more comprehensive information about health effects and experimental studies, (4) describes current sampling and analytical methods and their limitations for assessing occupational exposures to respirable crystalline silica, and (5) suggests many areas for further research.

Current sampling and analytical methods used to evaluate occupational exposure to respirable crystalline silica do not meet the accuracy criterion needed to quantify exposures at concentrations below the NIOSH REL of 0.05 mg/m^3 as a time-weighted average (TWA) for up to a 10-hr workday during a 40-hr workweek. Until improved sampling and analytical methods are developed for respirable crystalline silica, NIOSH will continue to recommend an exposure limit of 0.05 mg/m^3 to reduce the risk of developing silicosis, lung cancer, and other adverse health effects. NIOSH also recommends minimizing the risk of illness that remains for workers exposed at the REL by substituting less hazardous materials for crystalline silica when feasible, by using appropriate respiratory protection when source controls cannot keep exposures below the NIOSH REL, and by making medical examinations available to exposed workers.

Executive Summary

Occupational exposures to respirable crystalline silica occur in a variety of industries and occupations because of its extremely common natural occurrence and the wide uses of materials and products that contain it. At least 1.7 million U.S. workers are potentially exposed to respirable crystalline silica [NIOSH 1991], and many are exposed to concentrations that exceed limits defined by current regulations and standards.

Silicosis, usually a nodular pulmonary fibrosis, is the disease most associated with exposure to respirable crystalline silica. Although the reported mortality associated with silicosis has declined over the past several decades, many silicosis-associated deaths still occur (nearly 300 deaths were reported each year during the period 1992–1995) [NIOSH 1996a; Althouse 1998]. In addition, the number of silicosis-associated deaths among persons aged 15 to 44 has not declined substantially [CDC 1998a,b]. An unknown number of workers also continue to die from silica-related diseases such as pulmonary tuberculosis (TB), lung cancer, and scleroderma. The number of cases of silicosis and silica-related diseases in the United States today is unknown.

Symptoms of acute silicosis, another form of silicosis, may develop shortly after exposure to high concentrations of respirable crystalline silica. Epidemiologic studies focus on chronic silicosis, which develops years after exposure to relatively low concentrations of respirable crystalline silica. Epidemiologic studies have found that chronic silicosis may develop or progress even after occupational exposure has ceased [Hessel et al. 1988; Hnizdo and Sluis-Cremer 1993; Hnizdo and Murray 1998; Ng et al. 1987; Kreiss and Zhen 1996; Miller et

al. 1998]. Over a 40- or 45-year working lifetime, workers have a significant chance (at least 1 in 100) of developing radiographic silicosis when exposed to respirable crystalline silica at the Occupational Safety and Health Administration (OSHA) permissible exposure limit (PEL), the Mine Safety and Health Administration (MSHA) PEL, or the National Institute for Occupational Safety and Health (NIOSH) recommended exposure limit (REL).*

Silicosis may be complicated by severe mycobacterial or fungal infections. About half of these are caused by *Mycobacterium tuberculosis* and result in TB. Epidemiologic studies have firmly established that silicosis is a risk factor for developing TB.

The carcinogenicity of crystalline silica in humans has been strongly debated in the scientific community. In 1996, the International Agency for Research on Cancer (IARC) reviewed the published experimental and epidemiologic studies of cancer in animals and workers exposed to respirable crystalline silica and concluded that there was “sufficient evidence in humans for the carcinogenicity of inhaled crystalline silica in the form of quartz or cristobalite from occupational sources” [IARC 1997]. In the same year, directors of the American Thoracic Society (ATS) adopted an official statement that described the adverse health effects of exposure to crystalline silica, including lung cancer [ATS 1997]. The ATS found that “the available data support the conclusion that silicosis produces increased risk

*See appendix for the OSHA and MSHA PELs. The NIOSH REL is 0.05 mg/m³ as a time-weighted average (TWA) for up to a 10-hr workday during a 40-hr workweek.

for bronchogenic carcinoma.” However, the ATS noted that less information was available for lung cancer risks among silicotics who had never smoked and for silica-exposed workers who did not have silicosis. They also stated that it was “less clear” whether silica exposure was associated with lung cancer in the absence of silicosis. NIOSH has reviewed the studies considered by IARC and ATS, and NIOSH concurs with the conclusions of IARC [1997] and the ATS [1997]. These conclusions agree with NIOSH testimony to OSHA, in which NIOSH recommended that crystalline silica be considered a potential occupational carcinogen [54 Fed. Reg.* 2521 (1989)]. Further research is needed to determine the exposure-response relationship between lung cancer in nonsmokers and occupational silica dust exposure and to determine why lung cancer risks appear to be higher in workers with silicosis. The cellular mechanisms for development of lung cancer after crystalline silica exposure have been explored in many experimental studies and are not yet fully understood.

Statistically significant excesses of mortality from stomach or gastric cancer have been reported in various occupational groups exposed to crystalline silica. However, no conclusion about an association has been reached because most studies did not adjust for the effects of confounding factors or assess an exposure-response relationship for crystalline silica. The same problem exists for the infrequent reports of statistically significant numbers of excess deaths or cases of other nonlung cancers in silica-exposed workers.

Occupational exposure to respirable crystalline silica is associated with chronic obstructive pulmonary disease, including bronchitis and emphysema. The results of some epidemiologic studies suggest that these diseases may be less

frequent or absent in nonsmokers. Exposure to respirable crystalline silica is not associated with asthma.

Significant increases in mortality from nonmalignant respiratory disease (a broad category that can include silicosis and other pneumoconioses, chronic bronchitis, emphysema, asthma, and other related respiratory conditions) have been reported for silica-exposed workers [Checkoway et al. 1997, 1993; Chen et al. 1992; Cherry et al. 1998; Brown et al. 1986; Costello and Graham 1988; Costello et al. 1995; Costello 1983; Steenland and Brown 1995b; Steenland and Beaumont 1986; Thomas and Stewart 1987; Thomas 1990] and silicotics [Goldsmith et al. 1995; Brown et al. 1997; Rosenman et al. 1995].

Many case reports have been published about autoimmune diseases or autoimmune-related diseases in workers exposed to crystalline silica or workers with silicosis. In addition, several recent epidemiologic studies reported statistically significant numbers of excess cases or deaths from known autoimmune diseases or immunologic disorders (scleroderma, systemic lupus erythematosus, rheumatoid arthritis, sarcoidosis), chronic renal disease, and subclinical renal changes. The pathogenesis of autoimmune and renal diseases in silica-exposed workers is not clear.

Various other health effects (such as hepatic or hepatosplenic silicosis, extrapulmonary deposition of silica particles, liver granulomas, hepatic porphyria, cutaneous silica granulomas, pulmonary alveolar proteinosis, podocytosis, and dental abrasion) have been reported in studies of silica-exposed workers, but these effects have not been studied in depth with epidemiologic methods.

This Hazard Review also provides an abbreviated review of experimental research studies conducted to identify the molecular mechanisms responsible for the development of

*Federal Register. See Fed. Reg. in references.

silicosis and lung cancer. The results of these studies indicate the need for (1) additional long-term carcinogenesis studies in animals to determine dose-response relationships and (2) in vivo and in vitro studies to develop effective cellular and molecular models of carcinogenesis.

Although a large body of published literature describes the health effects of crystalline silica, some areas require further research. Many uncertainties exist, including (1) mechanisms and the influence of particle characteristics on development of disease; (2) toxicity and pathogenicity of nonquartz crystalline silica, silica substitutes, and dust mixtures; (3) translocation of particles from the lung; and (4) dose/exposure-response relationships in animals and in humans. In addition, further information is needed about (1) methods for reducing dust exposures in a wide variety of industries and the feasibility of implementing such methods, (2) methods for effectively communicating to workers the dangers of inhaling silica dust and

the importance of using appropriate control technologies and other protective measures, and (3) exposure sampling and analytical methods that will allow quantification of crystalline silica at low airborne concentrations (currently these techniques do not meet the accuracy criterion needed to quantify exposures at concentrations below the NIOSH REL).

Until improved sampling and analytical methods are developed for respirable crystalline silica, NIOSH will continue to recommend an exposure limit of 0.05 mg/m^3 to reduce the risk of developing silicosis, lung cancer, and other adverse health effects. NIOSH also recommends minimizing the risk of illness that remains for workers exposed at the REL by substituting less hazardous materials for crystalline silica when feasible, by using appropriate respiratory protection when source controls cannot keep exposures below the NIOSH REL, and by making medical examinations available to exposed workers.

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Abbreviations

ACGIH	American Conference of Governmental Industrial Hygienists
AMG	alpha-1-microglobulin
ATS	American Thoracic Society
BAL	bronchoalveolar lavage
BMG	beta-1-microglobulin
BMI	body mass index
°C	degree(s) Celsius
CA	chromosomal aberration(s)
cc	cubic centimeter
CDC	Centers for Disease Control and Prevention
CEN	European Standardization Committee
CFR	Code of Federal Regulations
CI	confidence interval
cm	centimeter(s)
COC	census occupation code
COPD	chronic obstructive pulmonary disease
Cu	copper
CV	coefficient of variation
\overline{CV}	pooled coefficient of variation
CWP	coal workers' pneumoconiosis
DE	diatomaceous earth
DLCO	diffusing capacity of the lung for carbon monoxide
DNA	deoxyribonucleic acid
EPA	U.S. Environmental Protection Agency
°F	degree(s) Fahrenheit
FEV ₁	forced expiratory volume in 1 second
FVC	forced vital capacity

g	gram(s)
HIV	human immunodeficiency virus
HLA	human leukocyte antigen
<i>hprt</i>	hypoxanthine-guanine phosphoribosyl transferase
hr	hour(s)
HSE	Health and Safety Executive (United Kingdom)
HVLV	high-velocity/low-volume
IARC	International Agency for Research on Cancer
ICD-9	International Classification of Diseases, 9th edition
Ig	immunoglobulin
IGLV	immunoglobulin lambda-variable chain
ILO	International Labour Organization
IR	infrared absorption
ISO	International Organization for Standardization
K_{α}	electron ionization energy
KBr	potassium bromide
kv	kilovolt(s)
L	liter(s)
LOD	limit of detection
m	meter(s)
mA	milliamp(s)
MDHS	Methods for the Determination of Hazardous Substances (Health and Safety Executive, United Kingdom)
mg	milligram(s)
$\text{mg}/\text{m}^3 \cdot \text{yr}$	milligrams per cubic meter times years
min	minute(s)
ml	milliliter(s)
mm	millimeter(s)
mppcf	million particles per cubic foot
MSHA	Mine Safety and Health Administration
NAG	beta-N-acetyl-D-glucosaminidase

NIOSH	National Institute for Occupational Safety and Health
NIST	National Institute of Standards and Technology
NMRD	nonmalignant respiratory disease
NOES	National Occupational Exposure Survey
NOHSM	National Occupational Health Survey of Mining
NOMS	U.S. National Occupational Mortality Surveillance
NTM	nontuberculous mycobacteria
OR	odds ratio
OSHA	Occupational Safety and Health Administration
<i>P</i>	probability
PAP	pulmonary alveolar proteinosis
PAT	proficiency analytical testing
PDGF	platelet-derived growth factor
PEL	permissible exposure limit
PMR	proportionate mortality ratio
ppm	parts per million
PVC	polyvinyl chloride
RDS	respirable dust standard
REL	recommended exposure limit
RF	radio frequency
RFLP	restriction fragment length polymorphism
ROS	reactive oxygen species
RSD	relative standard deviation
$\overline{\text{RSD}}$	pooled relative standard deviation
SCE	sister chromatid exchange
SCG	single cell gel/comet
SIC	standard industrial classification
SiO ₂	silicon dioxide
SIR	standardized incidence ratio
SMR	standardized mortality ratio

SRR	standardized rate ratio
TGF	transforming growth factor
TB	pulmonary tuberculosis
THF	tetrahydrofuran
TWA	time-weighted average
U.K.	United Kingdom
U.S.	United States
VC	vital capacity
WASP	Workplace Analysis Scheme for Proficiency
WHO	World Health Organization
wk	week(s)
XRD	X-ray diffraction
yr	year(s)
μg	microgram(s)
μm	micrometer(s)
%	percent

Glossary

Aerodynamic diameter: The diameter of a sphere with a density of 1 g/cm³ and with the same velocity (due to gravity) as the particle of interest [EPA 1996]. Particles of a given aerodynamic diameter move within the air spaces of the respiratory system identically, regardless of density or shape [NIOSH 1995a].

Chronic obstructive pulmonary disease (COPD): Includes airways diseases such as asthma, chronic bronchitis, and emphysema and is characterized by airways dysfunction [Becklake 1992].

Clearance: The translocation and removal of deposited particles from the respiratory tract.

Concentration: The amount of a substance (e.g., dust particles) contained per unit volume of air.

Confidence interval (CI), confidence limits: A range of values (determined by the degree of presumed random variability in the data) within which the value of a parameter (e.g., a mean or relative risk) is believed to lie with the specified level of confidence. The boundaries of a confidence interval are the confidence limits [Last 1988]. These include the lower confidence limit and the upper confidence limit.

Crystalline silica (or free silica): Silicon dioxide (SiO₂). “Crystalline” refers to the orientation of SiO₂ molecules in a fixed pattern as opposed to a nonperiodic, random molecular arrangement defined as amorphous. The three most common crystalline forms of silica encountered in the workplace environment are quartz, tridymite, and cristobalite [NIOSH 1974].

ILO category: The determination of profusion of small opacities observed by reading chest radiographs according to classification of pneumoconioses guidelines developed by the International Labour Organization (ILO). The latest classification guidelines were published by the International Labour Office in 1980 [ILO 1980].

Incidence: The frequency with which new cases of a disease occur in a given time period.

Incidence rate: The rate at which new events occur in a population. The number of new events (e.g., new cases of a disease diagnosed or reported during a defined period) is divided by the number of persons in the population in which the cases occurred [Last 1988].

Inhalable dust: The particulate mass fraction of dust in the work environment that can be inhaled and deposited anywhere in the respiratory tract.

Nontuberculous mycobacteria: Mycobacteria species other than the *Mycobacterium tuberculosis* complex (e.g., *Mycobacterium avium* complex).

Prevalence: The number of disease cases in a specific population at a particular time [Last 1988].

Prevalence rate (ratio): The total number of all individuals with an attribute or disease at a given time or during a given period divided by the population at risk of having the attribute or disease at this point in time or midway through the period [Last 1988].

Proportionate mortality ratio (PMR): Ratio of the proportion of deaths from a specific cause in an exposed population compared with the corresponding ratio in the nonexposed population. For example, the proportion of deaths from disease X in the exposed population could be compared with the proportion of deaths from disease X in the nonexposed population [NIOSH 2000].

Quartz: Crystalline silicon dioxide (SiO_2) not chemically combined with other substances and having a distinctive physical structure.

Respirable crystalline silica: That portion of airborne crystalline silica that is capable of entering the gas-exchange regions of the lungs if inhaled; by convention, a particle-size-selective fraction of the total airborne dust; includes particles with aerodynamic diameters less than approximately 10 μm and has a 50% deposition efficiency for particles with an aerodynamic diameter of approximately 4 μm .

Sarcoidosis: A rare multisystem granulomatous disease characterized by alterations in the immune system [Fanburg 1992].

Scleroderma (progressive systemic sclerosis): A rare multisystem disorder characterized by inflammatory, vascular, and fibrotic changes usually involving the skin, blood vessels, joints, and skeletal muscle [Archer and Gordon 1996].

Standardized mortality ratio: The ratio of the number of deaths observed in the study population to the number of deaths expected if the study population had the same rate structure as the standard population [Last 1988].

Standardized rate ratio: A rate ratio in which the numerator and denominator rates have been standardized to the same (standard) population distribution [Last 1988].

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